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DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN: 1124217
Facility ID: 141721
Inspection ID #1417210005

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3461

April 26, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Joseph A. Backer, M.D., Director of Mammography
Arlington Hospital
1701 North George Mason Drive
Arlington, Virginia 22205

Dear Dr. Backer:

A representative from the Commonwealth of Virginia under contract to the Food and Drug Administration (FDA) inspected your facility on April 18, 2000. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings:

- **Processor QC records were missing for 5 consecutive days in June 1999, for the [redacted] in which mammographic films were processed.**

- **Processor QC records were missing for 5 out of 10 days in June 1999, for the [redacted], in which mammographic films were processed.**

The specific problems noted above appeared on your MQSA Facility Inspection Report issued to your facility at the close of the inspection. These problems are identified as Level 1 findings because they identify a failure to comply with significant MQSA requirements.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, they represent a violation of the law that may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to, placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

In addition, your response should address the following Level 2 finding that was listed on the inspection report provided to you at the close of the inspection:

- **Radiologic Technologist [redacted] failed to meet the continuing education requirement of having completed a minimum of 15 continuing education credits in mammography in a 36- month period. [redacted] may not perform unsupervised mammography examinations until the continuing education requirements have been met.**

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- The specific steps you have taken to correct the violations noted in this letter.
- Each step your facility is taking to prevent the recurrence of similar violations.

Your response should be submitted to:

Food and Drug Administration
900 Madison Avenue
Baltimore, Maryland 21201
Attn: Nancy Rose
Compliance Officer

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have technical questions about mammography facility requirements or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, extension 159.

Sincerely,

Patrick V. McCarthy
Acting Director, Baltimore District